

Sub 1. A radially expandable fluid delivery device comprising:
a member constructed of a biocompatible material, the member having a longitudinal axis and a wall having a thickness extending between an inner and an outer surface, the wall having a microstructure of nodes interconnected by fibrils, the member being deployable from a first, reduced diameter configuration to a second, increased diameter configuration,

wherein the wall of the member includes at least one microporous portion having a porosity sufficient for a fluid to permeate through the wall, spaces between the nodes substantially controlling the permeation of fluid through the wall.

2. The fluid delivery device of claim 1, wherein the biocompatible material is ePTFE.

3. The fluid delivery device of claim 1, wherein the member has a hydrophilic exterior surface.

4. The fluid delivery device of claim 1, wherein the member has a hydrophobic exterior surface.

5. The fluid delivery device of claim 1, wherein the nodes within the microporous portion are separated by an internodal distance, the internodal distance being approximately $1\mu\text{m}$ - $150\mu\text{m}$.

6. The fluid delivery device of claim 1, wherein substantially all of the nodes within the microporous portion are oriented such that spaces between the nodes form micro-channels extending from the inner surface to the outer surface of the wall.

7. The fluid delivery device of claim 1, wherein the nodes within the microporous portion are oriented substantially perpendicular to the longitudinal axis of the member.

8. The fluid delivery device of claim 1, wherein the micro-channels within the microporous portion of the wall are sized to permit the fluid to pass from the inner surface to the outer surface of the wall.

9. The fluid delivery device of claim 8, wherein the size of the micro-channels varies longitudinally.
10. The fluid delivery device of claim 8, wherein the size of the micro-channels varies circumferentially.
11. The fluid delivery device of claim 1, wherein the member deploys to the second configuration upon application of a fluid having a pressure of approximately 1 psi to 250 psi.
12. The fluid delivery device of claim 1, wherein the microporous portion of the wall has a porosity sufficient to allow fluid to pass therethrough at a flow rate of approximately 0.01 ml/min to 100 ml/min.
13. The fluid delivery device of claim 1, wherein the member has a unitary construction of generally homogenous material.
14. The fluid delivery device of claim 1, wherein the fluid includes a medicinal agent.
15. The fluid delivery device of claim 14, wherein the medicinal agent is selected from the group consisting of thrombolytics, antibiotics, antisense oligonucleotides, chemotherapeutics, surfactants, diagnostic agents, steroids, vasodilators, vasoconstrictors, and embolic agents.
16. The fluid delivery device of claim 1, wherein the microporous portion of the wall borders a second portion of the wall that is generally impermeable to the pressurized fluid.
17. The fluid delivery device of claim 1, wherein the wall further includes a second microporous portion having a porosity sufficient for the fluid to permeate through the wall.

18. The fluid delivery device of claim 17, wherein an impermeable portion of the wall is interposed between the microporous portion and the second microporous portion of the wall.

19. The fluid delivery device of claim 17, wherein the second microporous portion is spaced longitudinally from the microporous portion.

20. The fluid delivery device of claim 17, wherein the second microporous portion is spaced circumferentially from the microporous portion.

21. The fluid delivery device of claim 1, wherein the microporous portion has a hydraulic conductivity less than $1000 \text{ (cm}^4 / (\text{dyne} \cdot \text{s}) \cdot 10^{12})$.

22. The fluid delivery device of claim 21, wherein the hydraulic conductivity is less than $500 \text{ (cm}^4 / (\text{dyne} \cdot \text{s}) \cdot 10^{12})$.

23. The fluid delivery device of claim 21, wherein the hydraulic conductivity is less than $100 \text{ (cm}^4 / (\text{dyne} \cdot \text{s}) \cdot 10^{12})$.

24. The fluid delivery device of claim 1, wherein the fluid delivery device is a medical treatment device for treating a body vessel, the microporous portion has a hydraulic conductivity less than the hydraulic conductivity of the body vessel.

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ca 25. An expandable drug delivery device comprising:
a member constructed of a biocompatible fluoropolymer material, the member having a longitudinal axis and a wall having a thickness extending between an inner and an outer surface, the wall having a microstructure of nodes interconnected by fibrils, the member being deployable from a first, reduced diameter configuration to a second, increased diameter configuration upon application of an expansion force to the lumen, a least a portion of the wall having nodes oriented such that spaces between the nodes form generally aligned micro-channels oriented and extending from the inner surface to

the outer surface of the wall, the micro-channels being sized to permit fluid including a therapeutic agent to permeate from the inner surface to the outer surface of the wall.

26. A radially expandable fluid delivery device comprising:

a member constructed of a biocompatible fluoropolymer material, the member having a longitudinal axis and a wall having a thickness extending between an inner and an outer surface, the wall having a microstructure of nodes interconnected by fibrils, the member being deployable from a first, reduced diameter configuration to a second, increased diameter configuration upon application of an expansion force,

wherein the wall of the member includes a first microporous portion having a porosity sufficient for a fluid to permeate through the wall and a second microporous portion spaced apart from the first microporous portion and having a porosity sufficient for a fluid to permeate through the wall.

27. A radially expandable fluid delivery device comprising:

a member constructed of a biocompatible fluoropolymer material, the tubular member having a longitudinal axis and a wall having a thickness extending between an inner and an outer surface, the wall having a microstructure of nodes interconnected by fibrils, the member being deployable from a first, reduced diameter configuration to a second, increased diameter configuration upon application of an expansion force, the wall including a microporous portion having nodes oriented such that spaces between the nodes form micro-channels extending from the inner surface to the outer surface of the wall, the micro-channels being sized to permit a fluid to permeate from the inner surface to the outer surface of the wall,

wherein the size of the micro-channels varies circumferentially about the tubular member to provide regions of greater porosity within the microporous portion.

28. A method of manufacturing a radially expandable fluid delivery device, the method comprising the steps of:

forming a tube of biocompatible fluoropolymer material having a microstructure of nodes interconnected by fibrils through an extrusion and expansion process having selected process parameters, the tube having a porosity corresponding to the selected process parameters, the tube having a longitudinal axis and a wall having a radial

thickness transverse to the longitudinal axis and extending between an inner and an outer surface,

applying a radial expansion force to the tube to expand the tube from the initial diameter to a second diameter, and

removing the expansion force,

wherein the tube is radially expandable from a reduced diameter to the second diameter upon introduction of a pressurized fluid to the lumen of the tube.

29. The method of claim 28, wherein the step of forming the monolithic tube comprises the steps of:

creating a billet by blending a mixture of a fluoropolymer and a lubricant and compressing the mixture,

extruding the billet to form an extruded article having a longitudinal axis,

removing the lubricant from the extruded article,

expanding the extruded article to form the tube of biocompatible fluoropolymer material having a microporous structure, and

heat setting the tube.

30. The method of claim 29, further comprising varying at least one of the predetermined process parameters to form at least one microporous portion of the wall having a porosity sufficient for the pressurized fluid to permeate through the wall.

31. The method of claim 30, wherein the at least one process parameters is selected from the group consisting of lubricant density, lubricant viscosity, lubricant molecular weight, longitudinal stretch ratio and stretch rate.

32. The method of claim 29, wherein the step of expanding the extruded article further comprises

bilaterally stretching the extruded article in two opposing directions along the longitudinal axis to yield an article which is substantially uniformly stretched over a major portion of its length.

33. The method of claim 28, wherein the step of applying a radial expansion force includes
inserting a balloon into the tube, and
inflating the balloon to apply the radial expansion force to the tube.
34. The method of claim 33, wherein the balloon is expanded by inflation with a fluid.
35. The method of claim 33, wherein the balloon is constructed of an inelastic material.
36. The method of claim 33, further comprising
providing a mold having an internal cavity,
positioning the tube within the internal cavity, and
inflating the balloon within the tube while the tube remains positioned in the internal cavity.
37. The method of claim 36, wherein the internal cavity has a size and shape analogous to the predefined size and shape of the balloon.
38. The method of claim 36, wherein the step of radially expanding the tube plastically deforms the tube beyond its elastic limit.
39. The method of claim 28, wherein the step of applying a radial expansion force includes
inserting a second tube of extruded material into the tube, and
expanding the second tube to apply the radial expansion force to the tube.
40. The method of claim 39, wherein the tube and the second tube are heated to the glass transition temperature of the extruded material during the step of radial expansion.
41. The method of claim 39, further comprising
providing a mold having an internal cavity,

positioning the tube and the second tube within the internal cavity, and radially expanding the tube within the internal cavity.

42. The method of claim 41, further comprising heating the tube and the second tube to the glass transition temperature of the extruded material during the step of radially expanding the tube within the internal cavity of the mold.

43. The method of claim 28, further comprising heat setting the tube after the step of applying a radial expansion force to the tube.

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C3 44. A medical treatment device comprising:
a catheter having an elongated hollow tube defining an inflation lumen extending from a proximal end to a distal end, and

a balloon constructed of a biocompatible fluoropolymer material and attached to the distal end of the tube, the balloon having a wall having a thickness extending between an inner and an outer surface and a lumen in fluid communication with the inflation lumen of the catheter, the wall having a microstructure of nodes interconnected by fibrils, the balloon being deployable from a first, reduced diameter configuration to a second, increased diameter configuration,

wherein the wall of the balloon includes at least one microporous portion having a porosity sufficient for a fluid to permeate through the wall, substantially all of the nodes within the microporous portion being oriented substantially perpendicular to the longitudinal axis of the balloon.

45. A radially expandable fluid delivery device having a longitudinal axis and a wall transverse to the longitudinal axis, the fluid delivery device comprising:

a first layer of biocompatible material having a microstructure of nodes interconnected by fibrils, and

a second layer of biocompatible material having a microstructure of nodes interconnected by fibrils, the second layer overlying the first layer, the wall of the fluid delivery device extending between an inner surface of the first layer and an outer surface

of the second layer, the fluid delivery device being deployable from a first, reduced diameter configuration to a second, increased diameter configuration,

wherein the wall of the fluid delivery device includes at least one microporous portion having a porosity sufficient for a fluid to permeate through the wall, substantially all of the nodes within the microporous portion being oriented such that spaces between the nodes form generally aligned micro-channels oriented and extending from the inner surface of the first layer to the outer surface of the second layer, the micro-channels being sized to permit fluid to permeate from the inner surface of the first layer to the outer surface of the second layer.

46. The fluid delivery device of claim 45, wherein substantially all of the nodes within the microporous portion being are substantially perpendicular to the longitudinal axis of the member.

47. The fluid delivery device of claim 45, wherein the micro-channels within the first layer are sized differently than the micro-channels within the second layer.

48. The fluid delivery device of claim 45, wherein the node in the first layer are separated by a first internodal distance and the nodes in second layer are separated by a second internodal distance, wherein the first internodal distance is different from the second internodal distance.

49. The fluid delivery device of claim 45, wherein the biocompatible material of the first layer is different than the biocompatible material of the second layer.

50. A radially expandable fluid delivery device comprising:

a member constructed of a biocompatible material, the member having a longitudinal axis and a wall having a microstructure of nodes interconnected by fibrils, the member being deployable from a first, reduced diameter configuration to a second, increased diameter configuration,

wherein the wall of the member includes at least one microporous portion having a porosity sufficient for a fluid to permeate through the wall, the microporous portion having a hydraulic conductivity less than $1000 \text{ (cm}^4/(\text{dyne} \cdot \text{s}) \cdot 10^{12})$.

51. The fluid delivery device of claim 50, wherein the hydraulic conductivity is less than $500 \text{ (cm}^4 \text{ / (dyne} \cdot \text{s))} \cdot 10^{12}$.

52. The fluid delivery device of claim 50, wherein the hydraulic conductivity is less than $100 \text{ (cm}^4 \text{ / (dyne} \cdot \text{s))} \cdot 10^{12}$.